

REMARKS

Applicants continue to assert that the claims in this application are directed to patentable subject matter. Indeed, there is nothing in the checkered history of this application which indicates otherwise. While this application has now been pending for some six years, there has not been a single rejection raised by the Examiner which has provided a consistent barrier to allowance. To the contrary, the nature of the rejections in this case changes with almost every official action. Nothing can be more indicative of this than the fact that now, some six years into prosecution, the prior art now being applied for the first time against a single pending claim is prior art which was cited by the applicants in their second IDS on September 3, 1997! While applicants appreciate the fact that the Examiner should present the best possible case in support of the Patent Office's position, it is also submitted that applicants are entitled to prosecution in which the Examiner at least attempts to present his overall position on the basis of the best prior art of which the Examiner is aware. While this cannot always be done, it is clear that in this case prosecution has been unduly extended for no apparent reason. Again, this prior art was available for six years and has now been applied for the first time, but only after applicants have once again overcome yet another prior art rejection by the Examiner. At some point there must be an end to prosecution. Applicants submit that that point was reached some time ago.

Applicants will now present their position as to why the present rejections are entirely inadequate, and the claims now present in this application are directed to patentable subject matter. Hopefully this long and arduous prosecution can thus be put to rest.

Claims 84 and 86-92 have been rejected as being unpatentable under 35 U.S.C. § 112, second paragraph. The Examiner contends that these claims are indefinite, that in claims 80-89 [sic] "based" has no antecedent in claim 84, and that in claims 84 and 92 "substantially" is vague. In this regard, the Examiner states that it can mean as much as 49%, citing *E.W Bliss Co. v. Cold Metal Process Co.*, 122 U.S.P.Q. 238 (ND Ohio 1959). This rejection is respectfully traversed in view of the above amendments and arguments and for the reasons set forth hereinafter.

Initially, applicants have overcome the objection to claims 80-89 [sic] by deleting "-based" from the claims depending on claim 84; namely, claims 86-89; as well as from claim 92, which does not depend from claim 84.

As for the term "substantially," applicants have previously presented a clear basis for the allowance of these claims in their present form, and for the sufficiency of this claim language. There is no legitimate basis for this rejection. Indeed, issued U.S. patents are replete with this very word, and for good reasons. It is, in fact, a necessary word to provide realistic protection for patentees. While it is clear from the present specification that water and the other specific solvents must be excluded from the claimed transdermal delivery systems, it is, of course, virtually impossible to exclude all water therefrom, for example. The present specification describes in detail the precise reasons why such liquids must be kept out of these products. In addition, it is also clear from the case law that language such as "substantially" is perfectly acceptable in such circumstances, and does not violate the provisions of § 112. *In re Mattison*, 509 F.2d 563, 184 U.S.P.Q. 484 (C.C.P.A. 1975) is a case where the Board's application of § 112 to the language "substantially

increase the efficiency of the compound as a copper extractant" was reversed. In *Seattle Box Co., Inc. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 U.S.P.Q. 568 (Fed. Cir. 1984), later appeal 756 F.2d 1574, 225 U.S.P.Q. 357 (Fed. Cir. 1985), the court again confirmed the fact that use of "substantially equal to" was not indefinite. See also *Andrew Corp. v. Gabriel Elecs., Inc.*, 847 F.2d 819, 6 U.S.P.Q.2d 2010 (Fed. Cir. 1988). It is therefore respectfully requested that this objection be withdrawn.

In response to the overwhelming case law relied upon by the applicants, the Examiner cites a single case from the Northern District of Ohio alleging that the term "substantially" can mean as much as 49%, under the specific facts of that case. The problem with this, however, is that in the *Bliss* case, the court was discussing claims which were added six years after the application had been filed, and which included a term requiring "driving a nail substantially by tension on the strip." In the accompanying remarks, however, these claims were interpreted by the applicant himself to be precautionary claims to someone using the substance of applicant's invention, but asserting that the power supplied was "say only 49% of the total." The court thus concluded that these claims "should be limited to the range attributed to them by the inventor" and only extend slightly under the point where tension is supplying 50% of the total power." The unwillingness to extend below 49% was based purely on the "evidence in the file wrapper." No one would argue that the term substantially in this case could mean anything like 49%. This is not the *Bliss* case, but it is like the many cases relied upon by the applicants, all of which were decided by the Federal Circuit and its predecessor, and not by a single district court relying on a unique set of facts. In the present case, the Examiner would be punishing applicants by requiring

that "substantially" be deleted from claims 84 and 92, thus permitting someone to essentially infringe applicants' invention by including some small amount of water without altering the basic novel characteristics of the present invention. This is precisely what applicants are attempting to avoid, and since the courts, including the Federal Circuit, have consistently held that the term "substantially" does not render a claim indefinite, it is submitted that the Examiner's position with respect to claims 84 and 92 is not correct, and should be withdrawn.

Claim 92 has been rejected as being anticipated by WO 89/09051 ("WO '051"). The Examiner contends that the '051 patent teaches transdermal administration of selegiline and a matrix comprising the hydrophilic polymer of EP 155229 ("EP '229"), which is disclosed and cited as extrinsic evidence for a polyacrylic polymer where the active and a polymer are dissolved in a volatile organic solvent, citing page 15, lines 19-24 thereof. This rejection is respectfully traversed in view of the above amendments and arguments and for the reasons set forth hereinafter.

It is initially noted that claim 92 has now been amended to include the requirement of a "hydrophobic" acrylic polymer, as is set forth in claim 84. Since claim 84 has not been rejected over this or any other prior art, it would appear that there is now complete agreement that both of these claims are directed to patentable subject matter. It is thus noted that as far back as early 2000, claims in this application have been directed to the use of hydrophobic polymers. Indeed, after objecting to that term for some time, the Examiner then contended that Horstmann et al., U.S. Patent No. 5,230,898, obviated this invention. However, in an interview held with the Examiner on July 3, 2001 (an interview at which agreement to

allowance was ostensibly reached), the Examiner agreed that the "consisting essentially of" language in the claims would overcome Horstmann *et al.* precisely because of the difference between the hydrophobic polymers claimed in this application and the hydrophilic polymers of Horstmann *et al.* The newly cited WO 051, however, is inferior to Horstmann *et al.* in many ways, and once again is admittedly directed to hydrophilic polymers. However, applicants claims, now including claim 92, are restricted to adhesive formulations which are hydrophobic. The adhesive compositions of the present invention can, in fact, only contain the highly plasticizing drugs hereof if the adhesives are not swellable in water, as are the adhesives of WO '051. The hydrophilic materials of WO '051, like those of Horstmann *et al.*, are swellable polymers, and if used, would lead one directly away from the hydrophobic polymers of the present invention. The materials of WO '051 thus require moisture absorption, creating supersaturation within the materials thereof. Indeed, these arguments have previously been presented and accepted by the Examiner.

The fact is that the hydrophilic polymers described in the paragraph bridging pages 4 and 5 of WO '051 and as set forth in the European '229 application do not and cannot produce the improved compositions of the present invention, and withdrawal of this rejection is therefore respectfully solicited.

Claim 92 has been rejected as being anticipated by Hosaka *et al.* under 35 U.S.C. § 102(b). The Examiner contends that Hosaka *et al.* teaches an adhesive layer containing an amino-containing methacrylamide and active, and that nitroglycerin is disclosed. The Examiner concludes that solutions of active and polymer in an active organic solvent are specified in Examples 1 and 2 of column 5 thereof. This rejection is respectfully traversed in view of the above

amendments and arguments and for the reasons set forth hereinafter.

It is once again initially noted that Hosaka et al. has not been applied against claim 84, and that claim 92 is now also specifically limited to the hydrophilic polymers hereof. It thus appears that the Examiner is in agreement with applicants that this claim is now also in condition for allowance. In any event, the Hosaka et al. patent is essentially directed to the use of a specific copolymer of (meth)acrylamide having an amino group in the molecule which is said to exhibit specific properties for use in connection with hydrophilic drugs. Indeed, the background section of the Hosaka et al. patent teaches away from the use of "many of the acrylic pressure-sensitive adhesives" because they generally have poor hydrophilic properties, so that when a hydrophilic drug is incorporated into those adhesives it is liable to crystallize causing problems of adhesion, diffusion and drug liberation.

Turning to the narrow scope of the Hosaka et al. invention itself, there is no reference whatsoever to the use of any specific compositions for use in transdermal patches or the like in which highly plasticizing drugs are particularly significant. Thus, in the long list of drugs beginning at column 3, line 50, the Examiner has selected one of many (namely, nitroglycerine) because of its plasticizing properties. These drugs were selected by Hosaka et al., however, solely because of their hydrophilic nature, and there is no recognition whatsoever of the significance of combining applicants' acrylic polymer with low molecular weight, highly plasticizing drugs, and maintaining same substantially free of water and liquids with normal boiling points below processing temperature and equal to or greater than the normal boiling point of the low molecular weight drugs themselves. Indeed, the examples in

Hosaka *et al.* referred to by the Examiner do not employ any highly plasticizing drugs at all, nor is there any reference to the presence or absence of solvents of the nature required by these claims.

Significantly, not only does Hosaka *et al.* once again fail to specify the use of hydrophobic acrylic polymers, but to the contrary, this patentee states that in order to improve the capacity of dissolving the drug, "the copolymer may furthermore comprise hydrophilic alkoxypropyl(meth)acrylate copolymers. . ." (column 2, lines 47-48) (emphasis added). Furthermore, the specific N,N-dimethylaminopropylacrylamide referred to in Example 1 of Hosaka *et al.* is rather unlikely to be used in an adhesive patch itself in view of its toxicity and other possible problems. On an overall basis, it remains clear that, far from constituting an anticipatory reference, Hosaka *et al.* utterly fails to teach or suggest the presently claimed invention.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

Application No.: 08/883,075

Docket No.: BERTEK 3.0-025

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

By 

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